STATUS OF CLAIMS

Claims 1-104 are pending in the application. Claims 1-72 were withdrawn pursuant to an election requirement. Claims 73 and 87 have been amended. Support for the amendments to claims 73 and 87 is found, for example, in paragraph [0033] of the specification. There is no issue of new matter.

REMARKS

Rejections Over the Cited Prior Art

The following two new rejections under 102(a) and 103(a) constitute the complete set presently being applied to the instant application, all other rejections having been withdrawn by the Examiner.

Rejection Under 35 U.S.C. § 102(a) – Solomon et al.

Claims 73-74, 84, 95-97 and 103 are rejected under 35 U.S.C. § 102(a) as being anticipated by Solomon et al. (U.S. Pat. No. 6,261,271).

In response, Applicants respectfully traverse the rejections and their accompanying remarks. Solomon et al. does not teach the invention of the claims. Specifically, Applicant states that the rejection over Solomon et al. has been rendered moot by the amendment to independent claim 1. Solomon et al. fails to teach all of the elements of the present invention as claimed in amended independent claim 73, which is directed to

> …a first ***annular layer comprising a matrix polymer, an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor that form a single distinct matrix polymer region***, a first polymeric barrier layer at least partially covering an interior surface of said first annular layer and a second polymer barrier layer at least partially covering an exterior surface of said first annular layer. (emphasis added).

The Solomon et al. reference fails as an anticipatory reference because it does not disclose ***all*** of the features of the claimed invention. Specifically, Solomon et al. fails to teach an annular layer that contains ***all three components***: matrix polymer, the antimicrobial agent, and a microbial attachment/biofilm synthesis inhibitor to form a ***single distinct matrix polymer region***. Solomon et al. fails to teach an annular layer that contains all three components within that layer to form one distinct matrix polymer region. Rather, Solomon et al. teaches structures where each

layer has a different anti-infective agent. For example, looking at the very parts of Solomon et al. that are cited by the Examiner himself, Solomon et al. teaches that a "catheter having laminated polymeric layers on both sides of the base layer may be prepared by simultaneous extrusion of three layers through a suitable tri-layer die. Such a tri-layer tubing may have bulk distributed chlorhexidine in any one, two, or all three of the layers, which may be of different thickness, or, if desired, a different agent may be either bulk distributed or surface coated onto one or both of the laminated layers." (Solomon et al., col. 6, lines 15-22). When Solomon et al. speaks of a polymer having a "dual anti-infective activity," it is not speaking of dual agents in a ***single distinct matrix polymer region***. Rather, the "dual" activity is achieved by putting an anti-infective in ***two separate layers***—a bulk layer and a surface coating layer. For example, Solomon et al. states that "[t]he preferred catheter of the invention includes a polymer having both bulk distributed chlorhexidine and a chlorhexidine coating. This embodiment of the invention produces a dual anti-infective activity. The surface coating provides a readily available and rapid release of chlorhexidine. The bulk distributed chlorhexidine, due to the hydrophilic nature of the polymer, migrates slowly to the surface when the catheter is in contact with a body fluid and produces anti-infective activity of long duration." (Solomon et al., col. 6, lines 23-32). Nowhere does Solomon et al. teach a single polymeric matrix region containing ***both*** an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor. Thus, Solomon et al. fails to teach an element of the claimed invention and fails to anticipate claim 1.

Solomon et al. suffers from a second fundamental deficiency. It fails to teach a "microbial attachment/biofilm synthesis inhibitor." The Examiner mistakenly states that "chlorhexidine [is] one of the same materials currently disclosed for this purpose." This statement is factually erroneous. As would be appreciated by one of skill in the art, chlorhexidine is not a microbial attachment/biofilm synthesis inhibitor. Chlorhexidine is correctly identified in Applicant's specification as an "antimicrobial agent." (*see* paragraph [0038] of Applicant's specification). Examples of microbial attachment/biofilm synthesis inhibitors is provided in paragraph [0039] of the Applicant's specification. Chlorhexidine is ***not*** listed anywhere as a microbial attachment/biofilm synthesis inhibitor. Solomon et al. as well states that chlorhexidine as an "anti-infective agent." There is simply no evidence to support the Examiner's assertion that

the chlorhexidine of Solomon et al. is "one of the same materials currently disclosed for the purpose [of a microbial attachment/biofilm synthesis inhibitor].

Nowhere is there a disclosure of a microbial attachment/biofilm synthesis inhibitors within the four corners of Solomon et al. This claim feature is simply missing and chlorhexidine, despite the Examiner's assertion, is not a microbial attachment/biofilm synthesis inhibitor. Since this claim element is missing, Solomon et al. fails to be an anticipatory reference.

For a reference to anticipate a claim it must disclose ***each and every elemen***t of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978)(emphasis added). Solomon et al. simply does not.

The above comments apply directly to independent claim 73. All other rejected claims are dependent directly on claim 73 and the rejection of those claims fails at least because of the fundamental defect discussed above and further because of additional distinguishing features present in those dependent claims.

Rejection Under 35 U.S.C. § 103(a) – Modak et al. in view of Solomon et al.

Claims 73-75, 80-90, 94-99 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modak et al. in view of Solomon et al (U.S. Pat. No. 6,261,271). The Examiner asserts that Modak et al. discloses a stent as discussed above, except that Modak et al. is silent as to using extrusion to prepare the tubing and agent resulting in a homogeneous bulk distribution. The Examiner cites Solomon et al. as teaching a homogeneous melt for the purpose of distribution of the agent in the base polymer.

In response, Applicant respectively traverses the rejection and its accompanying remarks. Applicant states that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. Even assuming for the sake of argument that the combination of Modak et al. and Solomon et al. teach or suggest all of the claimed features of the claimed invention, there is no teaching or suggestion to make the modifications necessary to the device of Modak et al. to arrive at the claimed invention. Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed.

Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching as a guard against using hindsight in an obviousness analysis). However, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

Applicant states that making the Examiner's proposed modifications to the device of Modak et al. would render the device unsatisfactory for its intended purpose. The Examiner proposes the following: "substitute the extrusion method of Solomon et al in place of the dip coating method of Modak et al in order to distribution [sic] of the agent in the base polymer. Such a modification amounts to mere substitution of one agent distribution method for another within the are [sic] of implantable tubing (ureteral stents)." Such modification, however, would defeat the intended purpose of Modak et al.

Modak et al. is very clear that a solvent-based dip coating method is critical for success because of the inherent difficulties in creating medical articles with anti-infective coatings. Indeed, Modak et al. states

> Successful treatment of a medical article with a polymer comprising an anti-infective agent may be ***problematic***, particularly where the medical article has a hydrophobic surface. The adherence of the polymer may depend upon (1) the polymeric matrix in which the anti-infective agent is suspended; (2)

> compatibility (or lack thereof) between the agent-polymeric matrix and the surface of the article; (3) the solvent system; and (4) the thickness of polymer/anti-infective agent desirably applied. Furthermore, ***the rates of release of various anti-infective agents from diverse polymers may differ***. To address these ***issues***, the present invention provides for two different methods for treating medical articles: one-step method, and a two-step method, both of which are set forth below. (Modak et al., col. 5, lines 52-65).

Modak et al. carefully details its one-step method and two-step method, both of which constitute detailed and extensive solvent-based solutions involving "coating, dipping or soaking the article in a treatment solution of a hydrophilic polymer" (col. 6, lines 20-21), "coating, dipping or soaking the article in a treatment solution of a hydrophobic polymer" (col. 6, lines 63-64), or "treat[ing] with a solution comprising one or more silver compounds, triclosan and/or other chlorinated phenol, and optionally containing a biomedical polymer, dissolved in one or more solvents, wherein the solvent(s) selected is (are) capable of swelling the polymeric medical article to be treated; such a solution is referred to herein as an "impregnating solution" (which is a species of treatment solution), and the process by which the article is treated with triclosan and a silver compound is referred to as "impregnation" (col. 7, line 67 to col. 8, line 9).

Given such teaching as the backdrop, one of skill in the art would not be motivated to delete the dip coating solutions of Modak et al. in favor of an extrusion method of Solomon et al. since such substitution would be in contravention of the teachings of Modak et al. Further, one of ordinary skill in the art, given that Modak et al. teaches the "problematic" and complex nature of successfully creating a medical device using anti-infective agents, would not have a reasonable expectation of success that the claimed invention would result by such substitution.

Finally, Applicants respectfully state that the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn,* 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at

___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

> (A) Combining prior art elements according to known methods to yield predictable results;
>
> (B) Simple substitution of one known element for another to obtain predictable results;
>
> (C) Use of known technique to improve similar devices (methods, or products) in the same way;
>
> (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
>
> (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
>
> (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
>
> (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 2143 for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144 - § 2144.09 for additional guidance regarding support for obviousness determinations.

Applicants state that the Examiner has not supported his conclusion of obviousness based upon any of the above-articulated rationales. Given the disclosures of Modak et al. regarding the problems inherent in successful treatment of medical devices with polymers containing anti-infective agents, one of ordinary skill in the art would not find that the substitution of the dip coating method of Modak et al. with an extrusion method of Solomon et al. to be a "predictable solution" with a "reasonable expectation of success." Making this substitution would neither be "simple" nor would one of skilled in the art have a measure of confidence that the claimed invention would result. The Examiner has not shown any indicators of such predictability within the four corners of Modak et al., Solomon et al., or with any other form of evidence. Indeed, the teachings of Modak et al. do not teach or suggest that invention that is "obvious to try" choosing

from a finite number of identified, predictable solutions, with a reasonable expectation of success, but rather, that departing from the prescribed dip coating method that it teaches may be "problematic."

For the reasons above, it is respectfully requested that the Examiner reconsider and withdraw the rejection of the claims.

CONCLUSION

Applicants submit that Claims 73-104 are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application in general, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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